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The FiCTION trial: child oral health-related quality of life and dental anxiety across 3 treatment strategies for managing caries in young children.

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Abstract

Objectives: The FiCTION Trial compared co-primary outcomes (dental pain and/or infection) and secondary outcomes (child oral health-related quality of life [COHRQOL], child dental anxiety, cost-effectiveness, caries development/progression and acceptability) across 3 treatment strategies (Conventional with Prevention (C+P); Biological with Prevention (B+P); Prevention Alone (PA)) for managing caries in children in primary care. COHRQOL and child dental anxiety experiences are reported upon here.

Methods: A multi-centre, 3-arm parallel group, unblinded patient-randomised controlled trial of 3-7-year-olds treated under NHS contracts was conducted in 72 general dental practices in England, Wales and Scotland. Child participants (with at least one primary molar with dentinal caries) were randomised (1:1:1) to one of three treatment arms with the intention of being managed according to allocated arm for three years (minimum 23 months). Randomisation was via a centrally-administered system using random permuted blocks of variable length. At baseline and final visit, accompanying parents/caregivers completed a parental questionnaire including COHRQOL (16 item P-CPQ-16), and at every visit child-and parental-questionnaire-based data were collected for child-based dental trait and state anxiety. Statistical analyses were conducted on complete cases from the modified intention to treat (mITT) analysis set.

Results: 1144 children were randomised (C+P: 386; B+P: 381; PA: 377). The mITT analysis set included the 1058 children who attended at least one study visit (C+P: 352; B+P: 352; PA: 354). Median follow-up was 33.8 months (IQR 23.8, 36.7). The P-CPQ-16 overall score could be calculated after simple imputation at both baseline and final visit for 560 children (C+P: 189; B+P: 189; PA: 182). There was no evidence of a difference in the estimated adjusted mean P-CPQ-16 at the final visit which was, on average, 0.3 points higher (97.5% CI: -1.1 to 1.6) in B+P than C+P and 0.2 points higher, on average, (97.5% CI: -1.2 to 1.5) in PA than for C+P. Child dental trait anxiety and child dental state anxiety, measured at every treatment visit, showed no evidence of any statistically or clinically significant difference between arms in adjusted mean scores averaged over all follow-up visits.

Conclusions: The differences noted in COHRQOL and child-based dental trait and dental state anxiety measures across 3 treatment strategies for managing dental caries in primary teeth were small, and not considered to be clinically meaningful. The findings highlight the importance of including all 3 strategies in a clinician's armamentarium, to manage childhood caries throughout the young child's life and achieve positive experiences of dental care.

Introduction

Childhood dental caries is an important public health problem[1]; its treatment is expensive and time consuming. Globally, 60-90% of school-children have dental caries; the incidence of untreated disease affecting 555 million and 573 million children, in 1990 and 2015 respectively, is of concern. Caries of the primary dentition is most severe in children between the ages of 1 and 4 years[1]. Evidence on the trajectory of the disease shows that children who experience carious lesions in their primary dentition carry a greater burden of disease into adolescence and adulthood[2].

The majority of child dental care occurs in primary care environments and is conducted by general dental practitioners (GDPs) and their teams. There is a longstanding debate about the best way of managing caries in children's primary teeth, *per se*, and what constitutes best practice in primary care[3]. Current research evidence has questioned the suitability of restorative treatments with local anaesthetic, removal of tooth decay and fillings in primary care. This conventional approach does not reduce the child's experience of dental pain and/or infection[4,5], but causes patient management difficulties for GDPs providing treatment for child and parent[6]. For the family, parent and child, untreated caries affects and impairs their quality of life[7,8,9]. An urgent need for evidence-based guidance on the prevention and treatment of childhood dental caries has been acknowledged, noting that this should provide evidence for effective clinical management of childhood caries and advise on the most appropriate form of behavioural management, together with the effects of different treatment modalities upon child dental anxiety and child oral health-related quality of life.

In response, the UK's National Institute for Health Research's Health Technology Assessment programme commissioned research to examine 'the clinical- and cost-effectiveness of treatment' for childhood dental caries. A three-arm, parallel group, individually randomised controlled trial (FiCTION)[10,11], was proposed to compare conventional treatment together with 'best practice prevention' (C+P) with: [i] biological treatment (sealing-in caries) with 'best practice prevention' (B+P): and [ii] 'best practice prevention' alone (PA) (Box 1), using the primary outcomes of the incidence and number of episodes of dental pain and/or infection over the follow-up period.

The value of patient-reported observations on treatment experience is becoming widely accepted, and patient perspectives are seen as invaluable. Patient-reported outcome measures (PROMs) are included in the majority of trials to evaluate changes in the impact of the condition, following treatment, from the patient's perspective. Recognising the importance of measuring a range of impacts on children and their families of the three different caries management strategies, a series of secondary outcomes were also

assessed in FiCTION. The child and parent-reported outcomes (CaPros) of child oral health-related quality of life (COHRQoL), child dental trait and state anxiety are reported upon here. Accordingly, the aim of this paper is to report on the effect of the intervention upon the child and parent-reported outcomes (CaPros) of child oral health-related quality of life (COHRQoL), child dental trait and state anxiety, across the duration of the FiCTION trial.

Methods

Trial design and randomisation

FiCTION was a multi-centre, three-arm parallel group, participant-randomised controlled trial designed with participants allocated to one of the three arms in a 1:1:1 ratio using a central web-based randomisation system with stratification by dental practice. This was an open trial with no blinding of participating children, their parents or dental professionals carrying out treatment. The trial design and the trial protocol are described in full at http://www.nets.nihr.ac.uk/projects/hta/074403. [10]

Setting

The trial took place in primary dental care, where the majority of children's dentistry is conducted in Scotland, England and Wales. To be eligible, dental practices had to: [i] see and treat children aged three to seven years under National Health Service (NHS) contracts; [ii] see children with carious lesions in primary teeth; and [iii] have the infrastructure to support the trial (e.g. electronic patient management systems and internet access). The participating dental practices were chosen to reflect the socio-economic position, ethnicity and water fluoridation status of the target population[11] and grouped into five clinical centres (CCs) for management purposes.

Participants

Participants were children attending primary dental care for NHS dental treatment. They were aged between 3 and 7 years; had a high risk of dental caries with at least one primary molar with dentinal caries; had no dental pain and/or infection at presentation; and were regular attenders or new patients considered likely to return for follow-up.

Sample size

The original target sample size was based on the primary outcome of incidence of pain and/or infection during three years of follow-up and was modified, after slower-than-anticipated recruitment, from the original target of 1460 to 1113 participants. Full details of the sample size and the CONSORT flow diagram are given in Innes et al[11]. The comparisons for the secondary outcomes reported in this paper

were unpowered and hence exploratory. The CaPro secondary outcomes were measures of COHRQOL, child dental trait anxiety and child state anxiety (anticipatory and treatment-related anxiety).

Child oral health-related quality of life (COHRQOL) was assessed using the Parent-Caregivers Perceptions Questionnaire 16-item short form (P-CPQ-16)[12,13]. The P-CPQ-16 has satisfactory concurrent validity and good reliability with a Cronbach alpha of 0.88[13]. The P-CPQ-16 asks the parents to rate how, in the past three months, the child's oral health has affected their OHRQOL. The P-CPQ-16 has the four domains of oral symptoms, functional limitations, emotional well-being and social well-being, which include items such as 'being upset' or 'been worried about being left out'. The individual items are measured on a five-point Likert scale ('never' = 0, 'once or twice' = 1, 'sometimes' = 2, 'often' = 3, 'every day or almost every day' = 4 and 'don't know' = 7). Parents were asked to complete the P-CPQ-16 at the baseline visit and scheduled final visit or in a final non-attendance questionnaire.

Child dental anxiety was assessed in terms of both underlying dental trait anxiety and state dental anxiety. Dental trait anxiety is associated with personality traits and is more stable over time, whereas dental state anxiety is situational, anticipatory and treatment-related. Dental state anxiety fluctuates and tends to fall from the start to the end of treatment. It was important to assess both aspects of dental anxiety to have a comprehensive understanding of how child dental trait and state anxiety might vary over time and in relation to the intervention. The versions of the inventories and visual analogue scales to assess dental anxiety used a pictorial format. Evidence[15] has shown that very young children can successfully complete inventories which use pictorial scales.

The FiCTION practices were asked to explain the layout and the purpose of the questionnaires as whole to the parent and child at the first visit. The completion of the Modified Child Dental Anxiety faces (MCDASf) scale[15] was explained to the parents and the children at all subsequent visits where necessary, and this was done by the dental nurse in the waiting room. The dental nurses had been trained to assist the younger children, where required, to complete the MCDASf by providing age-appropriate explanations, to read out the questions but not to influence the child's response.

Child dental trait anxiety was thus assessed using the MCDASf scale[15]. Children were asked to rate their dental anxiety on a picture scale representing a 5-point Likert scale from relaxed/not worried (scoring 1) to very worried (scoring 5). The 8-item version has a Cronbach alpha of 0.84[15]. Since the last two questions of the standard version of MCDASf ask about conscious sedation and dental general anaesthesia, neither of which were relevant to FiCTION participants, these items were omitted[16]. The

total scores for the 6-item MCDASf ranged from 6 to 30, with lower scores indicating lower dental trait anxiety. MCDASf was completed by the child before treatment at baseline and at every visit.

Child dental state anxiety (anticipatory and treatment-related) was measured using rating scales. The wording of the question ensured that it was the anxiety associated with dental situation which was assessed. Thus, the child was asked to complete two faces-based, visual analogue scales both ranging from 'not at all worried', scoring 1, to 'very worried', scoring 3, for the following questions: i), 'Before you saw the dentist today, were you?' for anticipatory dental anxiety, and: ii) 'Thinking about your visit to the dentist today, were you?' for treatment-related dental anxiety.

Parent-reported child anticipatory dental anxiety was measured on two visual analogue, 5-point numerical scales from 'not worried' (scoring 1), to 'very worried' (scoring 5). Parents were asked 'Before seeing the dentist today do you think your child was?' for child anticipatory dental anxiety and for treatment-related dental anxiety, 'Thinking about being at the dentist today, do you think your child was?' The accompanying parent and child were asked to complete the rating scales independently at the start of each treatment visit and at the end of each treatment visit.

Trial registration:

The FiCTION pilot trial was initially registered in the ISRCTN registry (reference: ISRCTN77044005) on 27th January 2009 and extended to include the main trial on 8th May 2013[11,17].

Ethical considerations:

Ethical approval for the study was given by the East of Scotland Research Ethics Service in July 2012 (REC reference: 12/ES/0047); IRAS project ID: 103239. Following this, the appropriate local Research & Development approvals and site-specific assessments were obtained for all practices.

Statistical analysis:

Analyses were carried out according to a pre-defined statistical analysis plan (SAP)[10]. The analysis of the CaPros was conducted for complete cases from the modified intention to treat (mITT) analysis set. mITT was 'defined as all randomised children with at least one case report form completed and in the trial database (MACRO™), including protocol violators and ineligible randomised participants, retaining participants in their randomised treatment groups' [11].

For the P-CPQ-16, "don't know" responses were treated as missing and `participant subscale mean' imputation was used if at least 50% of items in a subscale were complete. MCDASf used a similar approach, but as it has no subscales this was effectively 'subject overall mean' imputation[11]. Cronbach's

alpha with 95% confidence intervals (5,000 bootstrap samples) was calculated for P-CPQ-16 and MCDASf using baseline complete case data to estimate reliability.

P-CPQ-16 and MCDASf were analysed using linear mixed effect models. The mean difference between randomised treatment arms at final visit or across the whole of the follow-up period was estimated. Anticipatory and treatment-related anxiety and worry were collapsed to binary variables (comparing all levels of worry to not worried) due to the distribution of observations in each category. These outcomes, measured at each visit, were modelled using mixed effects logistic regression with data presented as risk differences, with C+P as the comparator. A positive risk difference indicates a higher risk of worry in that arm than in the C+P arm. As the study was powered on a significance level of 2.5%, we report 97.5% CIs. All models were adjusted for age (years) at randomisation, time in the trial (years) and baseline score, to be consistent with the analyses of the co-primary outcomes and as pre-specified in the SAP. Treatment related measures were not adjusted for baseline because they were only measured post-treatment. Differences between dental practices were included as a random effect. Where outcomes were measured at each visit (i.e. MCDASf, anticipatory and treatment-related anxiety and worry), an additional random effect was added to account for repeated measures nested within child. Randomised treatment arm was included in the models as a factor with three levels, with the C+P arm as the reference group[11].

Results

Sample

Seventy-two general dental practices participated. Of the 7699 children who attended a screening appointment, 1144 (14.9%) were randomised into the three arms (C+P: 386; B+P: 381 and PA: 377 Of the 1144 randomised children, 86 did not return for any treatment, and so, 1058 eligible children (92.5% of those randomly allocated) comprised the mITT analysis set upon which subsequent analyses were based. At randomisation, 25.2% (266/1057) of children in the mITT analysis set were less than 5 years old. The participating children were balanced across the three arms at baseline for mean age, sex, ethnicity, mean scores for COHRQOL (P-CPQ-16) child dental anxiety (MCDASf) and caries experience (Table 1) and the subsets used for analysis reflected the children in the mITT dataset in terms of baseline characteristics (Supplementary Table 1). There was no evidence of an overall difference among the three treatment strategies for experience of, or number of episodes of dental pain and/or infection (or both) over the follow-up period (median (IQR) 33.8 (23.8, 36.7) months)[11].

The CaPro secondary outcome measures

Children and parents/caregivers completed questionnaires at every visit. Child questionnaires were returned for 88.1% (6793/7713) of visits, parental questionnaires were returned for 87.4% (6747/7713) of visits).

Child oral health-related quality of life: The Cronbach alpha for the total P-CPQ-16 was good at 0.80 (95% CI: 0.77 to 0.84), in this sample of participating parents. The P-CPQ-16 was included in the baseline and scheduled final visit parental questionnaires. Parental questionnaires were at least partially completed for 93.0% (984/1058) of baseline visits and for 93.3% (664/711) of scheduled final visits attended. Both baseline and final parental questionnaires were received from 59.2% (627/1058) of parents/caregivers. Just over half of the children in the trial (560/1058, 52.9%) had a P-CPQ-16 score, following imputation, at both baseline and final visit; these data constituted the complete case analysis set for the P-CPQ-16 outcome (C+P: 189; B+P: 189; PA: 182). For the P-CPQ-16, 26.7% of the baseline or final scores (1120 questionnaires) involved imputation, of which 265/1120 (23.7%) had only one or two items missing. One particular item in the functional limitations sub-scale "breathed through the mouth" was missing for 186/1120 (16.6%).; excluding this item from the scale, the level of imputation would have been 15.7% rather than 26.7%.

The mean (sd) P-CPQ-16 overall scores were 8.7 (6.5), 7.9 (6.2) and 8.2 (6.4) for C+P, B+P and PA respectively. By the end of the follow-up period, there was little change, on average, in scores. The mean (sd) P-CPQ-16 overall scores at the final visit were 7.1 (6.7), 7.1 (6.5) and 7.1 (6.1) for C+P, B+P and PA respectively (Figure 1). There was no evidence of a statistically or clinically significant difference in COHRQOL between B+P and C+P (adjusted mean difference [aMD] (97.5% CI): 0.27 (-1.08 to 1.62)) or between PA and C+P (aMD (97.5% CI): 0.17 (-1.20 to 1.53)). These estimated positive mean differences represent, on average, a very slightly poorer OHRQOL for children in the B+P and PA arms than with the C+P arm, but the differences noted were extremely small, not statistically significant and would not be considered to be clinically meaningful (Table 2).

Child dental anxiety

The Cronbach alpha for the six-item version of the MCDASf was acceptable at 0.74 (95% CI: 0.71 to 0.77), in this sample of children. The MCDASf (dental trait anxiety) scores were calculated, following imputation, for 84.7% (6532/7713) of visits. Only 7.7% (500/6532) were imputed. The child anticipatory and treatment-related dental state anxiety rating scales were completed for 85.9% (6626/7713) and 84.1%

(6487/7713) of visits respectively. The response rate for parent-reported child anticipatory dental anxiety was 82.8% (6388/7713).

Dental trait anxiety (MCDASf) means (sds) were 15.0 (5.3), 15.1 (5.5) and 15.4 (5.5) for C+P, B+P and PA respectively, averaged over all post-baseline visits (Table 2). There was no evidence of any statistically or clinically significant difference in mean child dental trait anxiety scores, averaged over all follow-up visits, when comparing B+P to C+P (aMD (97.5% CI): 0.07 (-0.74 to 0.59)) and PA to C+P (aMD (97.5% CI): 0.22 (-0.44 to 0.89)).

Child-reported anticipatory dental anxiety: At the baseline visit 29.5% (279/945) of children reported that they were 'worried' before seeing the dentist (Table 3). During the follow-up period, the proportion of visits where a child indicated they were worried before treatment increased to 33.6% (1850/5496) overall; 34.7% (681/1961) C+P, 35.0% (643/1832) B+P and 30.9% (526/1703) PA. There was no evidence of any statistically or clinically significant difference between arms in levels of anticipatory anxiety, averaged over all follow-up visits, when comparing B+P to C+P (adjusted risk difference [aRD] (97.5% CI): 0.02 (-0.04 to 0.07)) and PA to C+P (aRD (97.5% CI): -0.03 (-0.09 to 0.02)).

Parental-reported anticipatory dental anxiety: At baseline, 32.4% (279/860) of parents thought their child was 'worried' before treatment (Table 3). Prior to treatment visits during the follow-up period, parents indicated their child was 'worried' at 31.0% (1524/4901) of visits overall; 34.4% (581/1687) C+P, 30.7% (514/1674) B+P and 27.8% (429/1540) PA. There was no evidence of a statistically significant difference between B+P and C+P (aRD (97.5% CI): -0.04 (-0.09 to 0.02)). However, there was a statistically significant difference between the PA and C+P arm (aRD (97.5% CI); -0.06 (-0.11 to -0.003)), with parent-reported child anticipatory anxiety, on average, 6.0% lower in the PA arm than in the C+P arm.

Child-reported treatment anxiety: The proportion of visits where children reported being `worried' after treatment was 29.8% (1934/6487) overall; 30.9% (705/2277) C+P, 30.8% (674/2188) B+P and 27.4% (555/2022) PA (Table 3). There was no evidence of any statistically or clinically significant difference between arms in post-treatment worry between B+P and C+P (aRD (97.5% CI): -0.002 (-0.05 to 0.04)) or PA and C+P (aRD (97.5% CI): -0.04 (-0.08 to 0.01)).

Parent-reported child treatment anxiety: The proportion of visits where parents reported after treatment that their child had been `worried' was 33.3% (2167/6498) overall; 35.8% (811/2262) in the C+P, 32.6% (714/2188) in the B+P and 31.3% (642/2048) in the PA group (Table 3). There was no evidence of a

statistically significant difference between B+P and C+P (aRD (97.5% CI): -0.04 (-0.09 to 0.02)) or between the PA and C+P (aRD (97.5% CI): -0.04 (-0.10 to 0.01)).

Discussion

There was no evidence of a difference in the COHRQOL or child dental trait anxiety measures between treatment arms at the end of the follow-up period, and no evidence that COHRQOL or child dental trait anxiety had changed over the period of the trial. Parent-reported child anticipatory anxiety was statistically significantly lower, on average by 6%, in the PA versus the C+P arm at the end of the follow-up period but there were no other differences in anticipatory or treatment-related anxiety between the arms. In summary, the differences noted in the CaPros measures were small and were not considered to be clinically meaningful.

From the behavioural perspective, the child and parent-related outcomes assessing COHRQOL, child dental trait and state anxiety were important to capture as a measure of potential treatment impacts, particularly since the three treatment approaches differ substantially from one another in that one (C+P) may have required the use of local anaesthetic. Parents tend not to recognise dental anxiety in their children, with a propensity to under-report, which is why child self-reported measures were chosen[17], however, it was difficult to identify instruments appropriate and/or valid for the target age group which was 3-7 years at baseline. The MCDASf psychometric properties and cut-offs have been described for children from 5 years to 10 years of age[15] but not for younger children [20] and although the 8-item MCDASf scale had been shown to be a reliable and valid measure of child trait dental anxiety, the MCDASf used in this trial was a shortened 6-item form. The psychometric properties of the shortened 6-item version have not been fully investigated, however, the internal consistency of the 6-item MCDASf of 0.74 was acceptable[21,22] and together with the pilot study[23] gave some reassurances that this shortened version of the MCDASf was appropriate for participating children as young as 3 years of age. However, there remains a need for future work to develop an appropriate scale for very young children as described by Klingberg and Hwang[24].

The P-CPQ-16 scale assessed parental and caregiver perceptions of COHRQOL. In 2014, Thomson *et al*. contrasted the responsiveness and functionality of the Early Childhood Oral Health Impact Scale (ECOHIS) and P-CPQ-16 scales and found them to be similar and of good quality for internal consistency, reliability, validity and responsiveness[12]. However, when used for health services research, where child participants

experienced significant amounts of caries, as in FiCTION, the P-CPQ-16 did not have the shortcomings of ECOHIS[25].

There were some limitations to the trial and collection of child and parent reported data. Recruitment and retention of participants in RCTS is recognised as a significant challenge[18,19], especially among young children and in a relatively research-naïve environment such as primary dental care services. Some practices were involved for up to 5 years in the RCT and suffered study fatigue requiring greater levels of motivational input from research support staff and clinical leads. The trial length also had an impact on trial practice training, which sometimes required repetition or supplementation, in view of staff turnover, particularly in long-serving and vocational training practices. In addition, some secondary outcomes were measured only at baseline and the scheduled final visit and, as 33% of mITT participants did not attend their scheduled final visit, the opportunity to capture these data for those individuals was missed.

Given the small amount of missing data and its balance across the randomised treatment arms, simple imputation was unlikely to bias the analysis. Simple imputation allowed us to increase the sample size for a more robust analysis and avoid excluding questionnaires with only a few missing items.

In conclusion, the differences noted in the CaPros measures across the three treatment arms were small and not considered clinically meaningful despite the three treatment modalities tested having different levels of invasiveness within their protocols. The inclusion of CaPros was essential and has important implications for the treatment of the young child patient, confirming the findings of the FiCTION RCT; that all three multi-component treatment strategies were acceptable to children and parents and none provoked significantly more anxiety than another. Clinicians treating young children can be confident about the range of clinical options in their armamentarium for treating caries in primary teeth – that is, minimally invasive approaches as well as conventional strategies alongside aggressive prevention. The trial highlights the importance of preventing dental disease and the requirement to prioritise risk-based prevention at both the community and individual level.

For children in whom prevention of disease has not been possible, the findings highlight the importance of the various clinical management strategies for childhood caries across the young child's experience of dental treatment. Around one third of young children experience treatment-related anxiety, even in the absence of anticipated operative intervention.

It is postulated that this work shows the importance of child-centred needs assessments and the importance of providing the child with best practice prevention together with appropriate restorative treatment – biological and/or conventional - tailored to the child's behavioural and clinical needs.

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Box 1 Description of the 3 intervention arms in the FiCTION trial.

1. Best Practice Prevention Alone (PA). This involved four preventive components carried out according to current national guidelines: tooth brushing; dietary investigation, analysis and intervention; fissure sealants applied to permanent teeth; fluoride varnish applied to primary and permanent teeth. Within this arm there was no removal of carious tissue, no sealing-in of caries, and no restoration placement.
2. Conventional with Best Practice Prevention (C+P). This involved the administration of local anaesthetic (LA), complete removal of carious tissue mechanically, tooth preparation and placement of a restoration to restore the tooth. Best practice prevention was carried out as above.
3. Biological with Best Practice Prevention (B+P). Carious tissue was not removed but sealed-in to the tooth and separated from the oral cavity by application of an adhesive restorative material over the decay, or by covering the tooth with a preformed metal crown (PMC) cemented in place, without any local anaesthesia or tooth preparation using the Hall technique. Best practice prevention was carried out as above.

Figure 1: Boxplots of P-CPQ-16 score at baseline, final visit and change at final visit from baseline for the participants with both baseline and final data (n=560)

Table 1: Participant characteristics at randomisation, by randomised treatment arm [mITT analysis set n=1058]

Participant characteristic	n	Conventional with Prevention (C+P) n= 352	n	Biological with Prevention (B+P) n= 352	n	Prevention alone (PA) n= 354	n	Total n= 1058
Age (years)								
Mean (sd)	352	6.0 (1.3)	351	6.0 (1.3)	354	5.9 (1.2)	1057	6.0 (1.3)
Sex								
n (% female)	349	175 (50.1)	349	181 (51.9)	349	180 (51.6)	1047	536 (51.2)
Ethnicity								
n (%)	313		322		320		955	
White		236 (75.4)		248 (77.0)		243 (75.9)		727 (76.1)
Black		9 (2.9)		11 (3.4)		10 (3.1)		30 (3.1)
Indian, Pakistani or Bangladeshi		37 (11.8)		38 (11.8)		36 (11.3)		111 (11.6)
Chinese		5 (1.6)		3 (0.9)		3 (0.9)		11 (1.2)
Mixed race		11 (3.5)		13 (4.0)		13 (4.1)		37 (3.9)
Other		15 (4.8)		9 (2.8)		15 (4.7)		39 (4.1)
P-CPQ-16 (parent-reported)								
Mean (sd)	300	8.9 (6.7)	314	8.0 (6.3)	309	8.3 (6.2)	923	8.4 (6.4)
MCDASf (child-reported)								
Mean (sd)	336	13.8 (4.9)	324	14.2 (5.3)	329	14.3 (5.3)	989	14.1 (5.1)
$d_3$mft								
Mean (sd)	339	2.8 (2.7)	333	2.8 (2.7)	334	2.6 (2.6)	1006	2.7 (2.7)

Table 2: Descriptive statistics by randomised treatment arm and model estimates of mean differences in P-CPQ-16[a] and MCDASf [b] between randomised treatment arms adjusted for baseline, age at randomisation and time in study.

Secondary Outcomes	Time-point	Conventional with Prevention (C+P)		Biological with Prevention (B+P)		Prevention alone (PA)		B+P vs C+P	PA vs C+P
		n	Mean (sd)	n	Mean (sd)	n	Mean (sd)	Adjusted mean difference (97.5% CI)	Adjusted mean difference (97.5% CI)
Overall P-CPQ16[c,]	Baseline	189	8.7 (6.5)	189	7.9 (6.2)	182	8.2 (6.4)		NA
	Final visit	189	7.1 (6.7)	189	7.1 (6.5)	182	7.1 (6.1)	0.27 (-1.08,1.62)	0.17 (-1.20,1.53)
MCDASf[d]	Baseline	315	13.8 (4.9)	292	14.2 (5.3)	304	14.3 (5.4)		NA
	All visits except baseline	1933	15.0 (5.3)	1732	15.1 (5.5)	1635	15.4 (5.5)	-0.07 (-0.74,0.59)	0.22 (-0.44,0.89)

a. A random effect for practice is also included
b. Includes random effects for practice and participants within practices
c. 560 children with both a baseline and a final P-CPQ16 score were included in this model
d. 911 children with a total of 5300 post-baseline measures were included in this model; participants with either a missing baseline score or a baseline score only and no subsequent measures were excluded

Table 3: Descriptive statistics and estimates of the risk differences for child and parent reported pre- and post-treatment-related anxiety between randomised treatment arms adjusted for baseline[de], age at randomisation and time in study.

Secondary Outcomes	Timepoint	Conventional with Prevention (C+P)		Biological with Prevention (B+P)		Prevention alone (PA)		B+P vs C+P	PA vs C+P
		n[g]	Number reporting anxiety[g] (%)	n[g]	Number[g] (%)	n[g]	Number[g] (%)	Adjusted risk difference (97.5% CI)	Adjusted risk difference (97.5% CI)
Child-reported anticipatory dental anxiety[abc]	**Baseline**	322	93 (28.9)	310	93 (30.0)	313	93 (29.7)		NA
	All visits except baseline	1961	681 (34.7)	1832	643 (35.1)	1703	526 (30.9)	0.02 (-0.04,0.07)	-0.03 (-0.09,0.02)
Parent-reported child anticipatory dental anxiety[abd]	**Baseline**	281	80 (28.5)	289	100 (34.6)	290	99 (34.1)		NA
	All visits except baseline	1687	581 (34.4)	1674	514 (30.7)	1540	429 (27.9)	-0.04 (-0.09,0.02)	-0.06 (-0.11,-0.003)
Child reported treatment-related dental anxiety[ae]	**All visits**	2277	705 (31.0)	2188	674 (30.8)	2022	555 (27.4)	-0.002 (-0.05,0.04)	-0.04 (-0.08,0.01)
Parent-reported child dental treatment-related anxiety[af]	**All visits**	2262	811 (35.9)	2188	714 (32.6)	2048	642 (31.3)	-0.04 (-0.09,0.02)	-0.04 (-0.10,0.01)

a. Random effects were also included to account for the nested structure of the repeated measures within children and children within dental practices.

b. Children with either a missing baseline score or a baseline score only and no subsequent measures were excluded from the anticipatory anxiety models.

c. 945 children with a total of 5496 post-baseline measures were included in this model.

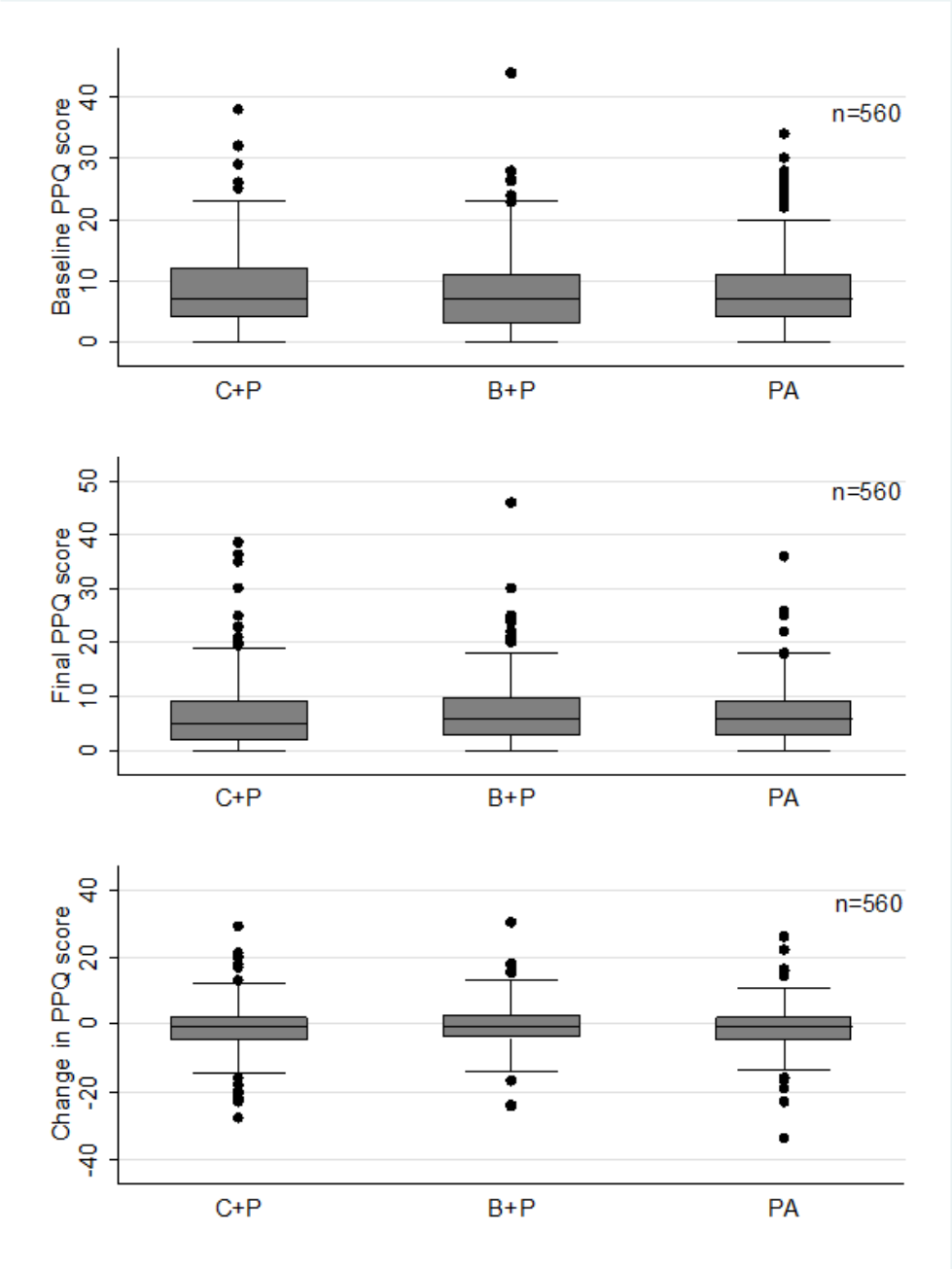
d. 860 children with a total of 4901 post-baseline measures were included in this model.

e. 1028 children with 6487 measures were included in this model. This model is not adjusted for baseline as “treatment-related” questions were collected at every visit.

f. 1030 children with 6498 measures were included in this model. This model is not adjusted for baseline as “treatment-related” questions were collected at every visit.

g. At baseline, n is the number of children and Number denotes the number of children with reported anxiety. For ‘all visits’, n is the total number of visits and Number is the number of visits where anxiety was reported.

Figure 1: Boxplots of P-CPQ-16 score at baseline, final visit and change at final visit from baseline for the participants with both baseline and final data (n=560)



The change in PPQ score is calculated as final visit score minus baseline visit score. A negative change indicates that the PPQ was lower at final visit (and hence the quality of life had improved).

Supplementary files

Table 1: Child and parent reported outcome measures by participant characteristics and arm of trial.